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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,380	08/30/2001	S. Grant Mulholland	10303-2 US	7757
7590 06/29/2004 DANIEL A. MONACO, ESQ. DRINKER BIDDLE & REATH, LLP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER LAM, ANN Y	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,380	MULHOLLAND ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-64 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) 65-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,13-26,28-34,40,44-53,55-64 and 73-75 is/are rejected.
- 7) ☒ Claim(s) 3-6,9-12,27,35-39,41-43 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6, 8-64 and 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, recites a "base member....adapted to prevent insertion of said base member into said urethra". It is unclear how the base member is adapted, i.e., modified, to allow it to perform the recited function. (Applicant would overcome this rejection by simply deleting "adapted".)

Likewise, for the same reasoning as mentioned above, the following are indefinite because of Applicant's use of the limitation "adapted": claim 1, line 10; claim 14, line 2; claim 33, line 3 and line 9; and claim 39, line 2.

Claims 61-64 are indefinite because claim 61 recites a "method....comprising the steps of: inserting the suppository of claims 1 or 33". It is unclear whether or not claims 61-64 incorporate all the limitations of claims 1 (or alternatively claim 33.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 8, 15, 18-21, 23, 32-34, 40, 45-48, 50, 58 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Finegold, 4,460,360.

As to claims 1, 33, 61 and 64, Finegold discloses a urethral suppository for insertion into a female urethra (column 4, line 14) comprising a non-meltable base member (72); a non-meltable reinforcement (66) having a length, said length having a first end (proximal portion of 66) and a second end (distal portion of 66), said first end attached to said base member and projecting from said base member (see Figure 4); and a meltable portion (62) formed around a portion of said length of said reinforcement (i.e., portion of 66 that is adjacent to 62, see Figure 4), said meltable portion having a diameter which tapers from said second end toward said first end (see distal end of 65 in Figure 4.)

As to claims 2, 34, the base member (72) is shaped for handling (column 4, line 17.)

As to claim 15, the second end of the reinforcement (66) extends outside the meltable portion (62).

As to claims 18-21, 45-48, the reinforcement (66) comprises a restraint.

Also, as to claim 61, a method for delivering therapeutic agents to the female urinary tract using the suppository is disclosed (column 4, lines 9-18.)

As to claim 32, 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes (column 4, lines 29-31.)

As to claims, 62 and 63, the device is inserted for about 1 minute to about 10 hours to deliver the therapeutic agent (column 4, lines 30-32.)

As to claims 8, 40, the base is comprised of polymer (column 4, lines 18-19.)

As to claims 23, 50, the meltable portion comprises anesthetics (column 4, line 9.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finegold, 4,460,360.

Finegold discloses the invention substantially as claimed (see above). More specifically, Finegold teaches that the "suppository 62 must be of sufficient length to extend the entire distance along a patient's urethra, and be of sufficient diameter to have complete contact with the inner surface of the urethra. The typical length of a

female urethra is 1 to 1/12 inches. The diameter of the suppository 62 should be from 8 to 10 french units."

With respect to claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75, Finegold does not disclose the specific dimensions as claimed. However, it would have been obvious to form the meltable portion having the dimensions as claimed, as would be necessary to fit inside the urethra of patients as taught by Finegold.

4. Claims 13 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finegold, 4,460,360, in view of Utley et al., 6,645,201.

Finegold discloses the invention substantially as claimed (see above). More specifically, Finegold discloses that member (66) may be formed from a plastic material (column 4, lines 17-18.) However, Finegold does not specifically disclose that the plastic is urethane.

Utley discloses that urethane is a type of medical grade plastic (column 18, lines 34-37.) It would have been obvious to form plastic member (66) in the Finegold device using specifically urethane as a known type of medical grade plastic as taught by Utley.

5. Claims 22 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finegold, 4,460,360, in view of Jackson et al., 4,542,020.

Finegold discloses the invention substantially as claimed (see above.) More specifically, Finegold discloses that suppository (62) dissolves at body temperature (column 4, lines 9-10.)

However, Finegold does not teach that the suppository (62) comprises cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10.) It would have been obvious to form the Finegold suppository from cellulose as a known material used in forming a suppository that melts when placed in a patient, as taught by Jackson.

6. Claims 26, 28, 29, 53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finegold, 4,460,360, in view of De Sushko, 1,767,785.

Finegold discloses the invention substantially as claimed (see above), except for helical grooves being formed in the meltable portion.

Sushko, like Finegold, discloses a urethral suppository. Sushko further discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.) It would have been obvious to provide helical grooves in the Finegold urethral suppository to retain the suppository inside the urethra as would be desirable for delivering medication to the urethra, as taught by Sushko.

Allowable Subject Matter

7. Claims 3-6, 9-12, 27, 35-39, 41-43 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Scott, 6,291,528, and Scott, 5,981,593, both disclose a suppository having a non-meltable base member, a non-meltable reinforcement, and a meltable portion for insertion into a urethra. Giglio, 5,085,650, Gordon, 3,126,887, Gearon, 1,537,992, and Place, 5,482,039, all disclose suppositories.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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6/26/04